

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group V in the reply filed on 3/19/2008 is acknowledged. Group III, drawn to pyrazolo[3,4-d]pyrimidines and simple compositions thereof, embraced by claims 14-19, 25 and 30 was elected by Applicant. Applicant pointed to the fact that Group I should have included claims 1-7 and Group II, claims 8-13. This is correct. However, Applicant has not pointed to any errors in the Examiners analysis of the classification of the different inventions. The requirement is thus deemed proper and is therefore made **FINAL**.

There are thirty claims pending and eight under consideration. Claims 14-19 and 25 are compound claims. Claim 30 is a composition claim. Claims 1-13, 20-24 and 26-29 are currently withdrawn from consideration. This is the first action on the merits. The application concerns some pyrazolo[3,4-d]pyrimidine compounds and simple compositions thereof.

This application contains claims 1-13, 20-24 and 26-29, drawn to an invention nonelected with traverse in the paper of 3/19/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: the phrase "optionally substituted alkylcycloalkyl" is repeated in lines 7 and 8. Appropriate correction is required.

Claim 1 is objected to because of the following informalities: the formula “NC<sub>1-6</sub>alkyl” is repeated on page 104, lines 7 and 8. Appropriate correction is required.

Claim 1 is objected to because of the following informalities: the formula “N,N-C<sub>1-6</sub>alkyl)sulfamoyl” is missing an open parenthesis. Appropriate correction is required.

Claim 1 is objected to because of the following informalities: the term “C<sub>1-6</sub>alkylsolfonylamino” is misspelled. Appropriate correction is required.

Claim 18 is objected to because of the following informalities: replace “NR<sup>21</sup>;or” with “NR<sup>21</sup>; or” in line 2. Appropriate correction is required.

Claim 18 is objected to because of the following informalities: the definition for R<sup>20</sup> is repeated in lines 6-7 in claim 18. Appropriate correction is required.

Claim 25 is objected to because of the following informalities: claim 25 is a substantial duplicate of anyone of claims 1-24 as the only difference is a statement of intended use, which is not given material weight. Note *In re Tuominen* 213 USPQ 89. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1624

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-19, 25 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the valency of the R<sup>5</sup> substituents is vague. The R<sup>5</sup> substituents named on page 104 of the claims are all trivalent. However, the R<sup>5</sup>-R<sup>5</sup> substituent has a divalent and trivalent R<sup>5</sup>. This is vague.

Regarding claim 1, the valency of the Het substituents is vague. The Het substituent is divalent with respect to Het-R<sup>5</sup> but trivalent as only Het. This is vague.

The Het substituent is not defined in the claims. Is this the same as heterocyclyl? Or does Applicant intend something else? This term is used throughout the claims.

The term "heterocycle" is the name of a compound; not a substituent. Please replace with the correct substituent name throughout said claims where applicable.

The term "vicinal-fused derivative" is vague. A derivative is a substance or compound

Art Unit: 1624

obtained from, or regarded as derived from, another substance or compound. What are these “vicinal-fused derivative?” Are the “derivatives” covered by the scope of the genus of formula (I)? See page 103, line 20.

Regarding claim 1, the term “preferably” is a range within a range. Thus, claim 1 is vague. See line 20.

The valency of the  $R^4$  is vague.  $R^4$  is shown in formula (III) has a trivalent substituent. However, the following variables are divalent: vicinal  $-OCH_2CH_2O-$ , vicinal  $-OC_{1-2}haloalkylO-$ , vicinal  $-OCH_2O-$ , and vicinal  $-CH_2OCH_2O-$ . Furthermore, the  $R^4$  position cannot be substituted with  $=O$ . This would exceed the valency of the carbon at the 5-position of the pyrazolopyridimidine bicycle.

The nitrogen in the formula “ $NC_{1-6}alkyl$ ” is vague. The valency of nitrogen is trivalent, not divalent. Thus, just a nitrogen atom at this position is not sufficient to maintain a neutral substituent at  $R^4$ .

The valency of the  $R^b$  is vague.  $R^b$  is defined with trivalent substituents on page 105. However, the following substituents show  $R^b$  as divalent:  $-C(=O)NR^a(R^bNR^aR^a)$ ,  $=C(=O)NR^a(R^bOR^a)$ ,  $-C(=O)NR^a(R^bS(=O)_nR^a)$ ,  $-C(=O)NR^a(R^bHet)$ ,  $-C(=O)OR^bNR^aR^a$ ,  $-C(=O)R^bNR^aR^a$ ,  $-S(=O)_2NR^a(R^bC(=O)NR^aR^a)$  and  $-S(=O)_2NR^a(R^bC(=O)OR^a)$ . This is vague.

The phrase, “optionally substituted” is vague. The definition on page 105, line 19, states that at least one substituent must be selected. How is this optional? Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

The term “(C<sub>1-4</sub>)S on page 105, line 23, is vague. What is the carbon count for?

Regarding claim 15, the substituent “S(=O)<sub>n</sub>R<sup>c</sup> lacks antecedent basis in line 3 of said claim.

Regarding variables R<sub>10</sub>, R<sub>11</sub>, R<sub>12</sub>, R<sub>13</sub> and R<sub>14</sub>, these variables are not defined in the claims but are found in formulas (i-iv and a-ab). Does Applicant intend the variables R<sup>10</sup>, R<sup>11</sup>, R<sup>12</sup>, R<sup>13</sup> and R<sup>14</sup>? Please keep the variables consistent throughout the claims if this is what Applicant intends. Furthermore, formula (iii) indicates an R<sub>11a</sub>, however, this variable is not defined. A variable R<sup>11a</sup> is defined but not found on any of the formulas. Thus, said variables are vague. See claims 16-18.

Regarding claims 17 and 18, the following variables lack antecedent basis on pages 108, 109 and 112:

Art Unit: 1624

$C(=O)NR^a S(=O)_2R^a$ ,  $C(=O)NR^aHet$ ,  $C(=O)NR^aNR^aR^a$ ,  $-C(=O)R^a-SR^a$ ,  $=S$ ,  $-NR^aC(=O)R^a$ ,  $-NR^aC(=O)OR^a$ ,  $-NR^aS(=O)_2R^b$ , and  $-S(=O)_2R^a$  in the definition of substituents on  $R^4$ .

The variable  $R^1$  is defined on page 109. However, this variable is not found in formula (III). See page 109, lines 16-19, claim 18. Thus, claim 18 is vague.

Regarding claim 18, the following variables lack antecedent basis on page 109:

$-CH_2$ -methylphenyl,  $-CH_2$ -phenol,  $-CH_2$ -(3,5-dimethylisoxazol-4-yl),  $-CH_2$ -S-phenyl,  $-CH_2$ -phenylcarboxyl, or  $-CH_2SCF_3$  in the definition of substituents on  $R^2$ .

The term " $CH_2$ -methylphenyl" is vague. What is this substituent? Is this a methylene toluyl? Or is this an ethylenlephenyl substituent? Thus, said term is vague.

Claims 1-19, 25 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant does not have support for "vicinal-fused derivatives, .... or vicinal -

Art Unit: 1624

OCH<sub>2</sub>CH<sub>2</sub>O-, vicinal – OC<sub>1-2</sub>haloalkylO-, vicinal -OCH<sub>2</sub>O-, and vicinal -CH<sub>2</sub>OCH<sub>2</sub>O-“ compounds. Where are these compounds in the Specification? The Specification does not provide specific description for “vicinal derivatives” and just a mere recitation of these compounds is not sufficient to comply with the written description requirement.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 16-18 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoneda et. al. (J. Chem. Soc. Perk. Trans., 1977, 7, 765-767).

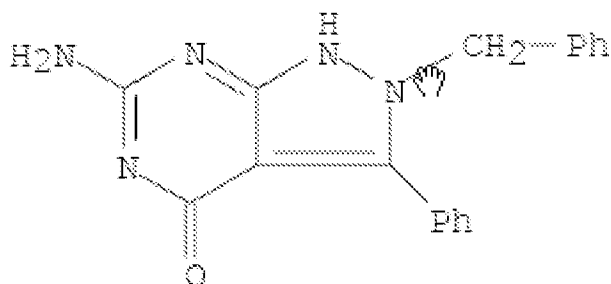
The reference teaches compounds of formula (I), wherein W= NH<sub>2</sub>, X= oxygen, R<sup>20</sup>= hydrogen, R<sup>4</sup>= phenyl and R<sup>3</sup>= phenyl.

RN 63603-95-2 CAPLUS

CN 4H-Pyrazolo[3,4-d]pyrimidin-4-one, 6-amino-2,5-dihydro-3-phenyl-2-

Art Unit: 1624

(phenylmethyl)- (9CI) (CA INDEX NAME)

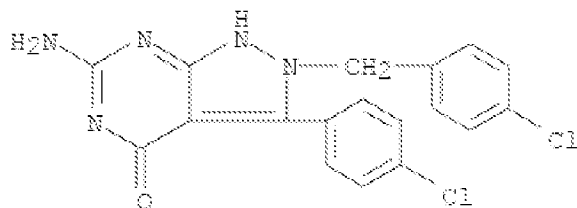


Also, the reference teaches compounds of formula (I), wherein W= NH<sub>2</sub>, X= oxygen,

R<sup>20</sup>= hydrogen, R<sup>4</sup>= 4-chlorophenyl and R<sup>3</sup>= 4-chlorophenyl.

RN 63603-96-3 CAPLUS

CN 4A-Pyrazolo[3,4-d]pyrimidin-4-one, 6-amino-3-(4-chlorophenyl)-2-[(4-chlorophenyl)methyl]-2,5-dihydro- (9CI) (CA INDEX NAME)



Furthermore, the reference teaches compounds of formula (I), wherein W= NH<sub>2</sub>, X=

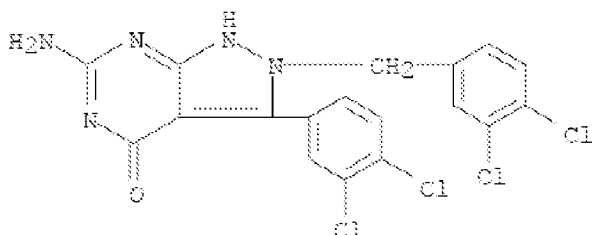
oxygen, R<sup>20</sup>= hydrogen, R<sup>4</sup>= 2,3-dichlorophenyl and R<sup>3</sup>= 2,3-dichlorophenyl.



Art Unit: 1624

RN 63603-97-4 CAPLUS

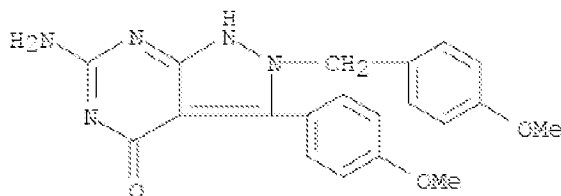
CN 4H-Pyrazolo[3,4-d]pyrimidin-4-one, 6-amino-3-(3,4-dichlorophenyl)-2-[(3,4-dichlorophenyl)methyl]-2,5-dihydro- (9CI) (CA INDEX NAME)



Furthermore, the reference teaches compounds of formula (I), wherein W= NH<sub>2</sub>, X= oxygen, R<sup>20</sup>= hydrogen, R<sup>4</sup>= 4-methoxyphenyl and R<sup>3</sup>= 4-methoxyphenyl.

RN 63603-98-5 CAPLUS

CN 4H-Pyrazolo[3,4-d]pyrimidin-4-one, 6-amino-2,5-dihydro-3-(4-methoxyphenyl)-2-[(4-methoxyphenyl)methyl]- (9CI) (CA INDEX NAME)



See the CAS printout provided for the compounds shown above. The reference is replete with species which the limitations of claim 14. Thus, said claims are anticipated by Yoneda et. al.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible

Art Unit: 1624

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-19, 25 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7285558. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus of formula (I) in the '558 patent is a subgenus of the genus in the instant Application.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/  
Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**